

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON PHARMACEUTICALS LTD. and)	
ALCON RESEARCH, LTD.,)	
)	
Plaintiffs,)	
)	
v.)	C. A. No. 12-960-UNA
)	
APOTEX INC. and)	
APOTEX CORP.,)	
)	
Defendants.)	

**DEFENDANTS APOTEX INC. AND APOTEX CORPORATION'S
ANSWER, DEFENSES, AND COUNTERCLAIMS**

Defendants-Counterclaim Plaintiffs Apotex Inc. and Apotex Corporation (collectively, “Apotex”) for their Answer, Defenses, and Counterclaims to the Complaint of Plaintiffs-Counterclaim Defendants Alcon Pharmaceuticals Ltd. and Alcon Research, Ltd. (collectively, “Alcon”) allege as follows:

1. Apotex admits that the Complaint purports to be an action alleging patent infringement arising out of Apotex’s filing of Abbreviated New Drug Application (“ANDA”) No. 90080, as amended, with the U.S. Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, importation, use, or sale of moxifloxacin hydrochloride sterile topical ophthalmic solutions, 0.5% as moxifloxacin base (the “Apotex Product”). Apotex denies any remaining allegations or legal conclusions in Paragraph 1, and specifically denies that the Complaint states a proper claim for patent infringement and denies that Apotex has infringed, does infringe, or will infringe any valid and enforceable claim of U.S.

Patent Nos. 6,716,830 (“the ’830 patent”) or 7,671,070 (“the ’070 patent”) (collectively, the “Asserted Patents”).

PARTIES

2. Apotex is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 2, and on that basis denies those allegations.

3. Apotex is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 3, and on that basis denies those allegations.

4. Apotex admits that Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Apotex also admits that Apotex Inc. is in the business of manufacturing and selling pharmaceutical products for the United States market. Apotex denies any remaining allegations in Paragraph 4.

5. Apotex admits that Apotex Corporation is a corporation organized and existing under the laws of Delaware and a wholly-owned subsidiary of Apotex Inc., having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex also admits that Apotex Corporation is in the business of manufacturing and selling pharmaceutical products for the United States market. Apotex denies any remaining allegations in Paragraph 5.

6. Paragraph 6 contains a statement to which no response is required.

7. Apotex admits that Apotex Inc. is in the business of manufacturing and selling pharmaceutical products for the United States market. Apotex also admits that ANDA No. 90080 was submitted for the purpose of obtaining FDA approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product. Apotex denies any remaining allegations in Paragraph 7.

8. Denied.

9. Apotex admits that Apotex Inc. and Apotex Corporation are in the business of manufacturing and selling pharmaceutical products for the United States market. Apotex denies any remaining allegations in Paragraph 9.

10. Apotex admits that Apotex Corporation is a wholly-owned subsidiary of Apotex Inc. Apotex also admits that Apotex Corporation is in the business of manufacturing and selling pharmaceutical products for the United States market. Apotex also admits that a webpage of Apotex Inc., located at <http://www.apotex.com/us/en/careers/default.asp>, states, among other things, as follows: “Apotex Inc. serves a marketplace of over 115 countries, and is committed to growth on a global basis through affiliates such as Apotex Corp. in the United States of America.” Apotex denies any remaining allegations in Paragraph 10.

11. Apotex admits that Apotex Corporation is a wholly-owned subsidiary of Apotex Inc. Apotex also admits that a webpage of Apotex Inc., located at <http://apotex.com/ca/en/bd/canadianbd.asp>, states, among other things, as follows: “We are a vertically integrated company. Our preference is to develop, manufacture and market our own products – from API to finished dosage form to marketing and distribution.” Apotex denies any remaining allegations in Paragraph 11.

12. Apotex admits that visitors of a website of Apotex Corporation, <http://www.apotexcorp.com>, are redirected to <http://www.apotex.com/us/en>, which is accessible to residents of the United States. Apotex denies any remaining allegations in Paragraph 12.

13. Apotex admits that it notified Alcon by letter dated June 7, 2012 (“Notice Letter”), of the submission and FDA acceptance of ANDA No. 90080 seeking FDA approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product. Apotex

also admits that the Notice Letter was signed by Apotex Inc. and designates an Apotex Corporation employee as its agent in the U.S. authorized to accept service of process for Apotex, limited to commencement of a patent infringement suit based on the Notice Letter. Apotex denies any remaining allegations in Paragraph 13.

14. Apotex admits that ANDA No. 90080 was submitted for the purpose of obtaining FDA approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product. Apotex denies any remaining allegations in Paragraph 14.

15. Apotex admits that Apotex Inc. and Apotex Corporation performed activities associated with the preparation and submission of ANDA No. 90080. Apotex denies any remaining allegations in Paragraph 15.

JURISDICTION AND VENUE

16. Paragraph 16 contains conclusions of law to which no response is required. Apotex will not contest subject-matter jurisdiction or venue for purposes of this action only. Apotex denies any remaining allegations or legal conclusions in Paragraph 16.

17. Paragraph 17 contains conclusions of law to which no response is required. Apotex will not contest personal jurisdiction for purposes of this action only. Apotex denies any remaining allegations or legal conclusions contained in Paragraph 17, and specifically denies that it has infringed, does infringe, or will infringe any valid and enforceable claim of the Asserted Patents.

18. Paragraph 18 contains conclusions of law to which no response is required. Apotex will not contest personal jurisdiction for purposes of this action only. Apotex denies any remaining allegations or legal conclusions in Paragraph 18.

19. Paragraph 19 contains conclusions of law to which no response is required.

Apotex will not contest personal jurisdiction for purposes of this action only. Apotex denies any remaining allegations or legal conclusions in Paragraph 19.

COUNT I-INFRINGEMENT OF THE '830 PATENT

20. Apotex incorporates its responses to each of the preceding Paragraphs 1-19 as if set forth herein.

21. Apotex admits that what appears to be a copy of the '830 patent was attached to the Complaint as Exhibit A, which on its face identifies April 6, 2004, as the date of issue by the U.S. Patent and Trademark Office; Alcon, Inc. as the assignee; and Gerald Cagle, Robert L. Abshire, David W. Stroman, and John M. Yanni as the named inventors. Apotex is without knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 21, and on that basis denies those allegations. Apotex specifically denies that the '830 patent was "duly and legally" issued.

22. Apotex is without knowledge or information sufficient to form a belief as to the allegations in Paragraph 22, and on that basis denies those allegations. Apotex specifically denies that it has infringed, does infringe, or will infringe any valid and enforceable claim of the '830 patent.

23. Apotex is without knowledge or information sufficient to form a belief as to the allegations in Paragraph 23, and on that basis denies those allegations. Apotex specifically denies that it has infringed, does infringe, or will infringe any valid and enforceable claim of the '830 patent.

24. Paragraph 24 contains conclusions of law to which no response is required.

Apotex denies any remaining allegations in Paragraph 24, and specifically denies that any claim of the '830 patent is valid and enforceable.

25. Admitted.

26. Apotex admits that it notified Alcon via the Notice Letter of the submission and FDA acceptance of ANDA No. 90080 seeking FDA approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product. Apotex denies any remaining allegations in Paragraph 26.

27. Apotex admits that it notified Alcon via the Notice Letter that ANDA No. 90080, as amended, includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") with respect to the '830 patent which speaks for itself. Apotex denies any remaining allegations of Paragraph 27.

28. Denied.

29. Apotex admits that ANDA No. 90080 was submitted for the purpose of obtaining FDA approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product. Apotex denies any remaining allegations in Paragraph 29.

30. Denied.

31. Denied.

32. Denied.

33. Denied.

34. Apotex admits that it has knowledge of the '830 patent. Apotex denies any remaining allegations in Paragraph 34.

35. Denied.

36. Denied.

37. Denied.

COUNT II-INFRINGEMENT OF THE '070 PATENT

38. Apotex incorporates its responses to each of the preceding Paragraphs 1-37 as if set forth herein.

39. Apotex admits that what appears to be a copy of the '070 patent was attached to the Complaint as Exhibit B, which on its face identifies March 2, 2010, as the date of issue by the U.S. Patent and Trademark Office; Alcon, Inc. as the assignee; and Gerald Cagle, Robert L. Abshire, David W. Stroman, and John M. Yanni as the named inventors. Apotex is without knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 39, and on that basis denies those allegations. Apotex specifically denies that the '070 patent was “duly and legally” issued.

40. Apotex is without knowledge or information sufficient to form a belief as to the allegations in Paragraph 40, and on that basis denies those allegations. Apotex specifically denies that it has infringed, does infringe, or will infringe any valid and enforceable claim of the '070 patent.

41. Apotex is without knowledge or information sufficient to form a belief as to the allegations in Paragraph 41, and on that basis denies those allegations. Apotex specifically denies that it has infringed, does infringe, or will infringe any valid and enforceable claim of the '070 patent.

42. Paragraph 42 contains conclusions of law to which no response is required. Apotex denies any remaining allegations in Paragraph 42, and specifically denies that any claim of the '070 patent is valid and enforceable.

43. Admitted.

44. Apotex admits that it notified Alcon via the Notice Letter of the submission and FDA acceptance of ANDA No. 90080 seeking FDA approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product. Apotex denies any remaining allegations in Paragraph 44.

45. Apotex admits that it notified Alcon via the Notice Letter that ANDA No. 90080, as amended, includes a Paragraph IV certification with respect to the '070 patent which speaks for itself. Apotex denies any remaining allegations of Paragraph 45.

46. Denied.

47. Apotex admits that ANDA No. 90080 was submitted for the purpose of obtaining FDA approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product. Apotex denies any remaining allegations in Paragraph 47.

48. Denied.

49. Denied.

50. Denied.

51. Apotex admits that it has knowledge of the '070 patent. Apotex denies any remaining allegations in Paragraph 51.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

COUNT III-DECLARATORY JUDGMENT
OF INFRINGEMENT OF THE '830 PATENT

56. Apotex incorporates its responses to each of the preceding Paragraphs 1-55 as if set forth herein.

57. Paragraph 57 contains conclusions of law to which no response is required. Apotex denies any remaining allegations contained in Paragraph 57, and specifically denies that it has infringed, does infringe, or will infringe any valid and enforceable claim of the '830 patent.

58. Paragraph 58 contains conclusions of law to which no response is required. Apotex denies any remaining allegations in Paragraph 58, and specifically denies that any claim of the '830 patent is valid and enforceable.

59. Apotex admits that it notified Alcon via the Notice Letter of the submission and FDA acceptance of ANDA No. 90080 seeking FDA approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product. Apotex denies any remaining allegations in Paragraph 59.

60. Apotex admits that it notified Alcon via the Notice Letter that ANDA No. 90080, as amended, includes a Paragraph IV certification with respect to the '830 patent which speaks for itself. Apotex denies any remaining allegations of Paragraph 60.

61. Apotex admits that ANDA No. 90080 was submitted for the purpose of obtaining FDA approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product. Apotex denies any remaining allegations in Paragraph 61.

62. Denied.

63. Denied.

64. Denied.

65. Denied.

66. Apotex admits that it has knowledge of the '830 patent. Apotex denies any remaining allegations in Paragraph 66.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

COUNT IV-DECLARATORY JUDGMENT
OF INFRINGEMENT OF THE '070 PATENT

71. Apotex incorporates its responses to each of the preceding Paragraphs 1-70 as if set forth herein.

72. Paragraph 72 contains conclusions of law to which no response is required. Apotex denies any remaining allegations contained in Paragraph 72, and specifically denies that it has infringed, does infringe, or will infringe any valid and enforceable claim of the '070 patent.

73. Paragraph 73 contains conclusions of law to which no response is required. Apotex denies any remaining allegations in Paragraph 73, and specifically denies that any claim of the '070 patent is valid and enforceable.

74. Apotex admits that it notified Alcon via the Notice Letter of the submission and FDA acceptance of ANDA No. 90080 seeking FDA approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product. Apotex denies any remaining allegations in Paragraph 74.

75. Apotex admits that it notified Alcon via the Notice Letter that ANDA No. 90080, as amended, includes a Paragraph IV certification with respect to the '070 patent which speaks for itself. Apotex denies any remaining allegations of Paragraph 75.

76. Apotex admits that ANDA No. 90080 was submitted for the purpose of obtaining FDA approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product. Apotex denies any remaining allegations in Paragraph 76.

77. Denied.

78. Denied.

79. Denied.

80. Apotex admits that it has knowledge of the '070 patent. Apotex denies any remaining allegations in Paragraph 80.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

REQUEST FOR RELIEF

Apotex denies that Alcon is entitled to any judgment or relief against Apotex and, therefore, specifically denies paragraphs (a) through (i) of Alcon's request for relief.

DEFENSES

First Defense (Non-infringement of the '830 Patent)

Apotex's proposed drug product described in ANDA No. 90080 has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and enforceable claim of the '830 patent, either literally or under the doctrine of equivalents.

Second Defense
(Invalidity of the '830 Patent)

Each claim of the '830 patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

Each claim of the '830 patent is also invalid as a result of non-statutory obviousness-type double patenting.

Third Defense
(Non-infringement of the '070 Patent)

Apotex's proposed drug product described in ANDA No. 90080 has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and enforceable claim of the '070 patent, either literally or under the doctrine of equivalents.

Fourth Defense
(Invalidity of the '070 Patent)

Each claim of the '070 patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

Each claim of the '070 patent is also invalid as a result of non-statutory obviousness-type double patenting.

Fifth Defense
(Failure to State a Claim)

Alcon's Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

Reservation of Rights

Apotex reserves the right to assert such other defenses that may appear as discovery proceeds in this case.

DECLARATORY JUDGMENT COUNTERCLAIMS

Counterclaim Plaintiffs Apotex Inc. and Apotex Corporation (collectively, “Apotex”), for their counterclaims against Counterclaim Defendants Alcon Pharmaceuticals Ltd. and Alcon Research, Ltd. (collectively, “Alcon”), allege as follows:

The Parties

1. Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.
2. Apotex Corporation is a corporation organized and existing under the laws of Delaware and a wholly-owned subsidiary of Apotex Inc., having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.
3. On information and belief, Alcon Pharmaceuticals Ltd. is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Route des Arsenaux 41, 1701 Fribourg, Switzerland.
4. On information and belief, Alcon Research, Ltd. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

Jurisdiction and Venue

5. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, under the United States Patent Laws, 35 U.S.C. § 1 *et seq.*, and under 21 U.S.C. § 355(j)(5)(C).

6. This Court has subject-matter jurisdiction based on 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and 21 U.S.C. § 355(j)(5)(C).

7. Alcon has submitted to personal jurisdiction in this Court by suing Apotex in this District and because Alcon Research, Ltd. is incorporated in this District.

8. This Court is the proper venue under 28 U.S.C. §§ 1391, 1367, 1400(b), and 21 U.S.C. § 355(j)(5)(C)(i)(II).

9. This is an action based on an actual controversy between Alcon and Apotex concerning the non-infringement and/or invalidity of U.S. Patent Nos. 6,716,830 (“the ’830 patent”) and 7,671,070 (“the ’070 patent”) (collectively, the “Asserted Patents”).

Background

10. This is an action for declaratory relief seeking a declaration of non-infringement and invalidity of the Asserted Patents.

11. Apotex submitted Abbreviated New Drug Application (“ANDA”) No. 90080, later amended to include a certification under 21 C.F.R. § 314.94(a)(12)(i)(A)(4) and 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV certification”), to the U.S. Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, importation, use, or sale of moxifloxacin hydrochloride sterile topical ophthalmic solutions, 0.5% as moxifloxacin base (the “Apotex Product”).

12. Alcon filed the instant Complaint in this Court alleging that Apotex’s act of submitting ANDA No. 90080, as amended, infringes the Asserted Patents and that any intended manufacture, use, sale, offer for sale, or importation of the Apotex Product will infringe the Asserted Patents.

13. Apotex denies that it has infringed, does infringe, or will infringe any valid and enforceable claim of the Asserted Patents.

14. Alcon asserted the '830 patent against Teva Pharmaceuticals USA, Inc. in this District over Teva's ANDA for an ophthalmic drug product containing moxifloxacin hydrochloride. *See Bayer Healthcare AG et al. v. Teva Pharms. USA, Inc.*, Civ. No. 06-234-SLR (D.Del.) (filed Apr. 5, 2006).

15. Alcon asserted the Asserted Patents against Watson Labs. Inc., Watson Pharmaceuticals, Inc., and Watson Pharma, Inc. in this District over Watson's ANDA for an ophthalmic drug product containing moxifloxacin hydrochloride. *See Alcon Pharms. Ltd. et al. v. Watson Labs. Inc. et al.*, Civ. No. 11-293-SLR (D. Del.) (filed Apr. 7, 2011).

16. Alcon asserted the Asserted Patents against Lupin Ltd. and Lupin Pharmaceuticals, Inc. in this District over Lupin's ANDA for an ophthalmic drug product containing moxifloxacin hydrochloride. *See Alcon Pharms. Ltd. et al. v. Lupin Ltd. et al.*, Civ. No. 11-587-SLR (D. Del.) (filed July 1, 2011).

17. Based on Alcon's filing of the instant Complaint against Apotex asserting infringement of the Asserted Patents, Apotex's denial thereof, and Alcon's history of asserting the Asserted Patents against other ANDA applicants for ophthalmic drug products containing moxifloxacin hydrochloride, an actual controversy now exists between Alcon and Apotex as to whether Apotex has infringed, does infringe, or will infringe any valid and enforceable claim of the Asserted Patents.

18. Unless enjoined, Alcon will continue to assert that Apotex infringes the Asserted Patents and will continue to impair Apotex's ability to market the Apotex Product, causing irreparable harm to Apotex's business.

The Asserted Patents and Vigamox[®]

19. The face of the '830 patent, titled "Ophthalmic Antibiotic Compositions Containing Moxifloxacin," indicates that it issued on April 6, 2004, from Application No. 10/200,868 filed on July 22, 2002, which was a continuation of Application No. 09/646,797 filed as Application No. PCT/US99/22622 on September 29, 1999, which purports to claim priority to U.S. Provision Application Ser. Nos. 60/102,506 and 60/102,504 filed on September 30, 1998.

20. The face of the '070 patent, titled "Method of Treating Ophthalmic Infections with Moxifloxacin Compositions," indicates that it issued on March 2, 2010, from Application No. 10/715,055 filed on November 17, 2003, which was a continuation of Application No. 10/200,868 filed on July 22, 2002, which is now the '830 patent.

21. On information and belief, Alcon Pharmaceuticals Ltd. purports to be the owner by assignment of the Asserted Patents.

22. On information and belief, Alcon Pharmaceuticals Ltd. purports to be the present holder of New Drug Application ("NDA") No. 21-598 for Vigamox[®], which is the trade name under which Alcon markets its ophthalmic drug product containing moxifloxacin hydrochloride in the United States.

23. Under 21 U.S.C. § 355(b)(1)(G), an NDA holder must provide to the FDA the patent number and expiration date of any patent(s) that it believes "claims the drug for which the applicant submitted the application or which claims a method of using such drug." The FDA publishes these patent(s) in an electronic, publicly available database called APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, also known as the "Orange Book."

24. The Asserted Patents are listed in the Orange Book with respect to Vigamox[®].

Apotex's ANDA No. 90080

25. Apotex submitted ANDA No. 90080 to the FDA seeking approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product, which has received tentative approval from FDA.

26. Apotex later amended ANDA No. 90080 to include a Paragraph IV certification seeking approval to engage in the commercial manufacture, importation, use, or sale of the Apotex Product in the United States prior to the expiration of the Asserted Patents.

27. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), Apotex provided notice of its Paragraph IV certification to Alcon by letter dated June 7, 2012.

28. On July 20, 2012, Alcon filed the instant Complaint against Apotex alleging infringement of the Asserted Patents.

29. The present suit by Alcon impairs Apotex's ability to obtain approval of its ANDA No. 90080 and to market the Apotex Product.

Count I
(Declaratory Judgment of Non-Infringement of the '830 Patent)

30. Apotex incorporates Paragraphs 1-29 of the Counterclaims as if fully set forth herein.

31. The Apotex Product has not infringed, does not infringe, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '830 patent, either literally or under the doctrine of equivalents.

32. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Apotex requests a declaration from the Court that Apotex has not infringed, does not infringe, and will not infringe any valid or enforceable claim of the '830 patent.

Count II
(Declaratory Judgment of Invalidity of the '830 Patent)

33. Apotex incorporates Paragraphs 1-32 of the Counterclaims as if fully set forth herein.

34. Each claim of the '830 patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

35. Each claim of the '830 patent is invalid as a result of non-statutory obviousness-type double patenting.

36. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Apotex requests a declaration from the Court that each of the claims of the '830 patent are invalid.

Count III
(Declaratory Judgment of Non-Infringement of the '070 Patent)

37. Apotex incorporates Paragraphs 1-36 of the Counterclaims as if fully set forth herein.

38. The Apotex Product has not infringed, does not infringe, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '070 patent, either literally or under the doctrine of equivalents.

39. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Apotex requests a declaration from the Court that Apotex has not infringed, does not infringe, and will not infringe any valid or enforceable claim of the '070 patent.

Count IV
(Declaratory Judgment of Invalidity of the '070 Patent)

40. Apotex incorporates Paragraphs 1-39 of the Counterclaims as if fully set forth herein.

41. Each claim of the '070 patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

42. Each claim of the '070 patent is invalid as a result of non-statutory obviousness-type double patenting.

43. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Apotex requests a declaration from the Court that each of the claims of the '070 patent are invalid.

DEMAND FOR JUDGMENT

WHEREFORE, Apotex respectfully requests judgment and relief in its favor against Alcon as follows:

A. Dismissing Alcon's Complaint with prejudice and denying each and every request for relief contained therein;

B. Declaring that any commercial manufacture, use, sale, offer for sale, marketing, or importation of the Apotex Product has not infringed, does not infringe, and will not infringe any valid or enforceable claim of the Asserted Patents;

C. Declaring that the claims of the Asserted Patents are invalid;

D. Enjoining Alcon, its officers, employees, agents, representatives, attorneys, and others acting on its behalf, from threatening or initiating infringement litigation against Apotex or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors,

or customers of Apotex, or charging them either orally or in writing with infringement of the Asserted Patents;

E. Declaring that this is an exceptional case, and that Apotex be awarded its attorneys' fees and costs pursuant to 35 U.S.C. § 285; and

F. Awarding to Apotex such further relief as this Court may deem necessary, just, and proper.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Adam W. Poff

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*Attorneys for Defendants Apotex Inc. and
Apotex Corporation*

Dated: July 23, 2012

CERTIFICATE OF SERVICE

I, Adam W. Poff, Esquire, hereby certify that on July 23, 2012, I caused to be electronically filed a copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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Attorneys for Plaintiffs

I further certify that on July 23, 2012, I caused a true and correct copy of the foregoing document to be served by e-mail on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

BY E-MAIL

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Dated: July 23, 2012

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